State of Maryland FINAL

Advisory Council on Prescription Drug Monitoring

Kaiser Permanente Columbia Gateway Medical Center

7070 Samuel Morse Drive

Columbia, Maryland 21046

October 2, 2009

9:30 a.m.

Before the Honorable John F. Fader, II, Chairman

Reported by: Lynne Livingston

Also in Attendance:

Dr. J. Ramsay Farah	LaRai Forrest Everett, Esq.
Donald Taylor	Dr. Robert L. Lyles, Jr.
Ellen L. Kuhn	Dr. Peter Cohen
Michael J. Wajda	Bruce Kozlowski
John J. Mooney	Georgette P. Zoltani
Janet Getzey Hart	Mary Johnson Rochee
Karen Thompson	Gail Amalia B. Katz
Alan Friedman	Ann Ciekot
Gwenn Herman	Delora Sanchez

(Whereupon, the meeting of the Advisory Council commmenced at 9:40 a.m.)

PROCEEDINGS

JUDGE FADER: I'll call this meeting to order. We are in fact missing a few people this morning. Who do you know who's not coming? Marcia's not coming.

MS. ZOLTANI: I think the other is (inaudible), but they're usually here.

JUDGE FADER: All right, I will entertain any comments on the minutes that Georgette prepared, and if there aren't any comments, corrections, I'd like to have a motion to approve.

DR. LYLES: I had one correction and I gave it to Georgette. Two people in the community, the names weren't there, and we'll add those.

MS. ZOLTANI: Yes, that has been corrected. Before I sent it, it was corrected.

DR. LYLES: Thank you.

JUDGE FADER: Okay. Anybody make a motion?

MR. KOZLOWSKI: So moved.

JUDGE FADER: Second?

DR. LYLES: Second.

JUDGE FADER: All in favor?

DR. FARAH: I need those names.

MS. ZOLTANI: By the way, we will have a transcript.

JUDGE FADER: Yes, we ran out of money but thanks to Georgette --

MS. ZOLTANI: And Michael.

JUDGE FADER: And Michael, we have obtained some more money so we're able to have this transcribed. Lynne is here and is taking care of us today.

And Lynne, although the names of the people are in front of them, we do have a number of visitors and those visitors, if they speak and forget to tell you their name, just say, may I have your name so we can have that transcribed.

Next we have a meeting in October, the 25th annual conference program of the NASCSA and

I'll have to find out what that.

MS. KATZ: That's the National Association of State Controlled Substances Authorities.

JUDGE FADER: Okay. And the brochure is here and over on the table. It is October the 20th through 23rd in San Diego at the Doubletree Hotel. Georgette has reserved money for two people to go from here, if you want to. It would be appreciated if someone would go, but we have that authority including plane and everything, Georgette?

MS. ZOLTANI: Yes. Yes, everything's covered.

JUDGE FADER: Okay. So if anybody can go it would be very much appreciated. There certainly are many more meetings associated with this around the country than I ever dreamed of. I mean it is just unbelievable, but there are a lot of them. So if you can do that and contact Georgette.

MS. KATZ: I can tell you two of the speakers. I just started reading this but David Jorgenson and Scott Fishman are extraordinary and

really leaders in the field of pain management and the interaction of access to pain medication.

JUDGE FADER: It's already been called to my attention that I'm in the year 1009. This is because I have to do all this typing myself now. I have no one to help me, so I have no one to pick up the mistakes, but I apologize for that.

What I prepared and handed out to you on the colored paper is the provisions from the Wiretapping and Surveillance Act, and also from the Confidentiality of Medical Records Act for the criminal and civil penalties for individuals who disseminate, publish wiretapping information obtained illegally, and also for the Medical Records Act.

Certainly the conference that I went to, that a number of us went to last week had everyone in unison saying that we have to ask the legislature that anyone who violates any of these confidentiality provisions that this is a felony with some pretty severe penalties. That seems to

be the way of most of the states do it, so I put here the penalties.

The next is what I put forth, and this has 19 pages which consists of a compilation of the directive from the legislature to us as to what information we are to give to the legislature in the report.

And the second part of it is the 2006 bill so that you can see that was the bill that was passed by the General Assembly but vetoed by Governor Ehrlich, and you can see what the provisions are there.

So I was hoping that what we could do today was to pretty much jump to page two and talk here about the first subject, to identify the drugs to be monitored to try to get the consensus of the committee, the council, for the advisory vote with the understanding that the final votes will be taken at that meeting in December.

But it seems to me that there are a number of alternatives here. First of all, number one,

that it would include Schedules II through V. Number two, that it would include Schedules II through V, plus whatever the secretary would want to designate as an abused drug put on the list.

Three, would go II through V, plus whatever would be passed by regulation. And you know you have a situation there, is it wise, is it not wise to put this into the hands of the Secretary of Health and Mental Hygiene without regulations or with regulations.

Regulations are notice to the community giving everybody an opportunity to weigh in on it, as opposed to the secretary having the authority to do that themselves.

Number four, you have the situation where drugs II through V, plus everything else in the world, which is the picture of what the patient is taking, and VI, VII and VIII, or whatever anybody else wants to suggest.

So maybe we can talk about that. One of the questions that I have of Bob and I have of

Ramsay here is, is it the considered judgment of the people in the field that having the patient's full prescription history available, including any other medications that the individual may be taking blood pressure, Cialis, whatever the medication is, would be important for patient care, and if so, the legislature is going to want to know if we do that, give us some examples that can be elaborated on.

And I forgot one thing, Judge Cathy Cox comes to me and wants to know the answer to a question. It's not a criminal case, it's a civil case that she has before her. The man had a knee replacement and a physician wrote for 300 Oxycontin tablets, and she says to me, is that usual? Isn't that a large amount of drugs? And I said, I don't know the answer to that question Cathy, but I've got a few friends that could weigh in on that. So maybe that's a good example of, I don't know the answer to that question.

DR. FARAH: Which part do you want us to start with?

JUDGE FADER: I want you to answer Judge Cox's question because she's very close to me.

DR. FARAH: Okay. What we need to know is what dose of Oxycontin is being prescribed and for what duration of time. Sometimes insurance covers only a three month supply at one time and so the doctor has to submit a three month supply because that's how the insurance covers it.

JUDGE FADER: Insurance will not cover any less than that?

DR. FARAH: No, they do, but you pay less co-pay if you get a three month supply, so that's one thing to know if it was prescribed that way.

Secondly, what's the dose? Are we taking about 10, 20, 30, 80?

JUDGE FADER: She did not know the dose.

DR. FARAH: Well, you see you need to know what dose.

And thirdly, you want to know what are the other medications being prescribed in conjunction with this based on what diagnosis and what's the

treatment plan. So I hate to look at a number and make a decision just from a number without knowing a little bit more.

It looks like a lot but we don't know. Is this a three months supply where you're getting only 100 a month of 20 milligrams.

DR. LYLES: What you are looking at when you look at number, and this is what I fear with prescription drug monitoring is that --

JUDGE FADER: So maybe she's asked a good question.

DR. LYLES: I have a patient that takes 10 milligram brand name Percocets, like $300. If I reduce it to generic 5 milligram Percocet it's $19. So I may do a combination of drugs to get affordability, and it will look like, what are you prescribing all this stuff for? I've got a patient that walks out with almost 500 tablets a month of 5 milligrams because the way that comes together it costs them less than $100 a month.

JUDGE FADER: My wife tells me she has

those same things at the pharmacy with some different drugs that the manufacturer comes out with as a combination that the patient cannot afford. The patient says I can't afford this and she says, well, wait a minute, let's call your physician. So she calls and she gets the two component drugs that make that up that are both generic now and the physician allows her to change it and then that's all much, much less money-wise.

DR. LYLES: And we're seeing in the inner city where the husband and wife come in together and they're getting one prescription for 100 milligrams of something and they really need 25 milligrams each and they're cutting the pills into four pieces for affordability. Now, can you criticize the doctor for that? Sure you can. But what you're providing is medical care for the community at some kind of an affordable price.

So these things really have to be taken on an individual basis, and if you're going to review every one of these, why have a doctor?

JUDGE FADER: Okay, but you see these are the kind of things that, I haven't filled a prescription in 40 years, so what do I know. And these are the types of things that we need to put notes in the report about things of this sort so that can also enhance Ramsay's important thrust to have a review for the enforcement people.

MR. TAYLOR: I think it's also a case where just knowing the number of tablets doesn't mean anything. You have to know the strength and B, you have to know the dosage. Because Oxycontin's normally BID twice a day. So if you took it right at that, you're talking a 5 month supply. But without knowing the dosage, without knowing --

DR. COHEN: And with seven different doses.

MR. TAYLOR: The other factors here, you can't say that that's too high or too low. But this would be a case where if I was a pharmacist filling it, I would want to be able to access the

patient's record and at least look at it.

DR. LYLES: And it may not be Oxycontin, it may be Oxycodone.

JUDGE FADER: No, she said it was Oxycontin because I asked her.

MS. KATZ: I think this is a perfect example of what's going to happen with this kind of a process in place and I think, you know, we would need to have a medical review panel that would be very accessible and would be paid. So you know, it adds a cost that I think we have not discussed in the past to the actual implementation of this kind of a program.

JUDGE FADER: Well, Cathy Cox is as bright as you can have anybody come along. When she asks a question that I certainly didn't know the answer to, I do remember now that Oxycontin comes in different doses. I had forgotten that for a while. But these types of examples and a few things like that need to go into footnotes in the report to indicate and emphasize the need for this

review.

All right. What drugs are going to be monitored?

DR. FARAH: Well, we started off by saying II to V seems to be the reasonable thing.

JUDGE FADER: That's all across the country.

DR. FARAH: Right. And then what else? What else, I'm thinking if you really want to have a powerful tool to help physicians, I think there are two classes of medications that are extremely helpful to be listed. One would be the medications that are commonly used for depression and anxiety and second, medicines that originally were created for epilepsy but are being used off label for mental health purposes such as Topamax, Depakote for migraine.

And you say why do you want to track these down? You want to track these down because when you add these medications, particularly some of the medications, when you add them to an opiate you do

something which is completely different, you increase the QTC interval. A lot of the deaths that are occurring are due to sudden cardiac death and that's due to the prolongation of QTC.

JUDGE FADER: Of what?

DR. FARAH: In the electrocardiogram the distance between --

JUDGE FADER: QTC?

DR. FARAH: QTC. These drugs interactions, a lot of doctors know all about and some they don't, but they look it up. But there are some subtle areas that can dramatically affect a certain situation totally unbeknownst to people.

One of course, the ammonia level may go up in patients who are receiving HIV drugs and receiving bipolar, or migraine, or depression medication such as Depakote. So you have HIV drugs, you have Depakote, but then these people have an addiction problem and they are either on methadone or on actual opiates and you see these high ammonia levels. People are walking around,

but you know what? They're going to drop dead at some point, totally --

JUDGE FADER: Well, even 40 years ago in pharmacy school we got told about synergistic effects.

DR. FARAH: Yes.

JUDGE FADER: And I imagine that some of that is still applicable here.

DR. FARAH: Absolutely. Not only synergistic effects, which is known in psychiatry as augmentation therapy, the other medication for example is Prozac or Zoloft or whatever, and you're giving the patient and they have depression or post-traumatic stress disorder and you want to add something else, then you add Wellbutrin to that, that will be an augmentation therapy.

It's synergistic, you get more benefit than either drug alone in the maximum dose you can give. This is very established in the mental health industry.

DR. LYLES: I was going to say it's

getting even more complicated than that. We're looking at now in the next ten years gene specific medicine. The focus of what we started with, was it six, seven years ago with this now, was basically law enforcement.

What we have is a social problem. Now the social problem has migrated into a public health problem, prescription drug abuse. That's migrating into how we're going to deal with this. Are we going to put everybody in jail? We can't do that, we can't afford it. But treatment is possibly an option. To adequately treat these people, because we're talking about mind-altering substances in many cases. Everything you talked about was mind-altering substances.

You talk about methadone and QT intervals, the general thinking now is not that this methadone, methadone is fine. What happens with methadone is you plunge the testosterone down. The testosterone is what's actually producing the cardiac dysfunction, the low testosterone. You get

an 18 year old who should have a testosterone of 1,000 or so, they come in with a testosterone of 100, hasn't had an erection in two years because he's been on methadone or one of the other drugs. If you treat the hormonal dysfunction along with the drug addiction then you may produce and progress towards a more healthy patient, has a sense of well being, a purpose in the community, possibly even going back to work.

So where do we want to go with all of this? My position is that we need to monitor every medication that they're on because there's no way else you can look at this from even a law enforcement point of view and go back and say this is what the problem is.

DR. FARAH: Well, let me tell you what we've learned. Let me tell you what we've learned so far. What we've learned so far is that there is a logistical, mechanical problem in documentation tracks and the degree of sophistication of pharmacy systems that can catch this information.

If you're going to put every medication, I can assure you at this time it is a death sentence on the project because there is no way we can have the technology and the money.

JUDGE FADER: Yeah, well Bruce is going to tell you respectfully he doesn't think that that's so because the system that's going to go into effect with the state is going to require all pharmacies to report all of this.

MR. KOZLOWSKI: If I might, just from a procedural standpoint, thinking forward to January and then thinking forward, what needs to go into a report at this juncture is an outline for process. What I think you're talking about now going beyond, with what drugs are included and what the protocols are, what you want to do in regulation. And you want to do it that way because if you don't, you will never be able to make changes without going into a changing legislative body that doesn't always remember the history.

So I guess what I'm saying is you can have

an awful lot of discussion time in recognizing that the statute requires the creation of an advisory board that is all inclusive.

JUDGE FADER: The 2004 statute required that.

MR. KOZLOWSKI: Right. And there's no question whatever would be done, logic would seem that that would always be the case, and that was the group that these series of questions and protocols ought to be working with, separate from what we're doing here.

If we lay out the basics of do we want to do this and when do we want to do this, how do we want to do this in the generic form the legislature can deal with it in the time frame that's there.

If you make there a technical report that gets down into the dynamics of what drugs are in and what drugs are out, the nuances of the protocols for access, the debate will go from committee to subcommittee into perpetuity and

nothing will take place.

JUDGE FADER: All right. But the directive of the legislature to us is identical to the drugs that should be monitored. So I think what's going to come from that is the consensus of the committee is, at least these drugs, but the necessity for an interdisciplinary committee to add other drugs, et cetera. Now the question is, what are we going to say?

MR. KOZLOWSKI: The Schedule drugs I think are the ones that this group can agree on, and the plus word, that there will be other drugs going through an interdisciplinary group. And I think that meets the intent of the legislature and provides you the segue into getting these matters resolved in a more flexible form.

The regulatory process is neat because once you make a decision there's a public comment period and you have to go back through the comment period, so that it's a very gracious process.

JUDGE FADER: What Ramsay and Bob are

saying is for the recommendation, they don't only want it to be II through V, they think it should be II through V plus anti-anxiety drugs, et cetera, is the best recommendation and then leave it up to the multidisciplinary board to put more on.

So the question is that's on the table for discussion and what we're going to recommend.

MS. KUHN: And just for purposes of transcription, my name is Ellen Kuhn and I'm filling in for Linda Bethman from the Attorney General's office today.

I agree with Bruce. I think if you go too far into the weeds it's going to be problematic. And while I hear you about anti-anxiety drugs, I think that that actually might be easier to deal with by regulation. So to put something, you know, to maybe make a recommendation these Schedule drugs, and other drugs, you know, as seen fit by the secretary and the committee promulgated through regulation will probably catch everything you're looking for because I think that committee is going

to catch these types of nuances that you're talking about.

DR. FARAH: Right. Putting everything on the table, there's a sell that is public acceptance, there is an avoiding a chilling effect, there is a usefulness for prescribers. People are very leery all the time in taking two years to make a change. Regulation does take two years to make a change.

So yes, I have no problem getting an initial list and then saying plus a select list through an advisory body. That's step two. But on step A, you want to sell a concept that is going to be productive, that is useful, which is something you can use, which is going to save lives, which is going to help patients, which is going to help doctors.

JUDGE FADER: Which is going to allow the best chance of treatment.

DR. FARAH: Exactly. And so I'm saying, look, I'm going to give you half of what you're

looking for and you know what, you can look forward to all the rest I'm going to give you. And I'm sitting here saying, yeah, what, two, three, four years from now? Come on.

MS. KUHN: We can do regulations in six months, six months for regulations.

JUDGE FADER: Six months for regulations.

DR. FARAH: With all due respect, I have been putting in regulations through the board for the last six years, I have never seen regulations get enacted in six months and I've been doing it for six years with the full staff of the board. Let's call it the way it is in Maryland today.

MR. KOZLOWSKI: Well, just a minute, I'm going to take exception to that.

MS. KUHN: I am, too.

JUDGE FADER: This is great, that is just like a bench meeting. Hold the bricks and everything so nobody throws anything.

MR. KOZLOWSKI: The regulatory protocol is very well spelled out, it works exceptionally well,

even to the point in which during the legislative session we were able to get the review board to review during the session. I don't think I can think back over the last four years that we have ever had a delay beyond six months to get regulations through. And I just put a whole load of them through in the last four or five months.

JUDGE FADER: All right, Alan?

MR. FRIEDMAN: I do have a comment but Peter's been waiting patiently, so.

JUDGE FADER: Peter's next, and then the DEA is going to talk. Go ahead.

DR. COHEN: Thank you. In my medical profession many of us complain about treating the paper, not the patient, and we engage ourselves in this to treat the database and not what is a very serious public health and criminal control problem.

I keep recommending going back to always not wanting to complicate things too much but also reminding us of what we are doing this for. One is

because we have a problem that's out of control and we have people who are getting out of control and we have certain predators who are using this to make money and creating disruption.

So what are we using this for? It's for physicians and other medical facilities to say, can I enhance my awareness. Who's using this for the right purpose and who isn't and whether I'm getting myself into a pickle of a situation, and for our criminal control, for want of a better term, criminal control purposes to say we think we've got something going on and we think we have, not beyond a reasonable doubt but a certain amount of suspicion that someone is using these medications for some other purpose, so let's look at that.

To put all these other medications on it, I can understand from a research and from a medical viewpoint, but I think that's too expensive. And creating databases are extremely expensive when there are other kind of community interactions and community public health interventions that you need

to do, including working with the medical profession.

So I would not want to extend it beyond the Schedule II. What I would want is a process if something like that happens and if you're calling a physician, nurse-practitioner, a physician's assistant, if you think there's something criminal going on, that there is a process of saying stop for a minute, talk a look at the case, and like you were mentioning with this particular doctor who prescribed 300 Oxycontin, there's a lot I want to know, age of the person, can they swallow a pill, all the things you would ask to say not beyond a reasonable doubt, forgive me for not knowing all about law, but knowing that there's something beyond a reasonable doubt.

JUDGE FADER: For most of the decisions that you make, it's by a preponderance of the evidence, 51 percent more likely so than not so.

DR. COHEN: Thank you. Would say that you would then be able to proceed to an investigate the

situation.

But you're saying from the medical viewpoint there's a preponderance of evidence to say that, but you have a place that says stop this for a minute, because what you don't want is the 300 oh, my goodness, let's find the witch.

JUDGE FADER: You also are in a situation with regard to medical care that you're less than a preponderance of the evidence. Well, you know, just sitting around the table over the past six months that there is a great difference of opinion with a lot of situations from people you respect as to how this should be treated or how that should be treated. Now that does not mean that all of those people that disagree with you are bad people, or bad physicians or bad practitioners, it just means that sometimes these options are open.

Okay, all right.

MR. FRIEDMAN: I understand that there's a desire to sell a concept. My concern is that we have two different concepts going on here and that

one of them may be outside of the scope of the group. So I think that there's certainly benefit in having the full patient profile to provide good medical care. The fact that I'm on an antibiotic tetracycline or an anti-inflammatory does not have necessarily bearing on whether I'm doctor shopping, scamming or abusing medication. Not to say that there aren't potential drug interactions between the anti-inflammatory and a pain medication. Certainly there can be and it can have an additive effect. But I thought the scope of the project was to look at --

JUDGE FADER: Yeah, it's on page one, identification of drug abuse, identification of drug diversion, balanced use to assist appropriate law enforcement activities while preserving the professional of practice of healthcare providers, preserving access of patients to optimal pharmaceutical care, so it can include that, okay.

MR. FRIEDMAN: Okay, well, that defines it for me a little bit better.

JUDGE FADER: That's the reason I did all this stuff and put all these things here is so that we can have this for discussion.

MR. FRIEDMAN: I think there needs to be consensus within the group about what the scope of the project is going to be, because it can be as big as you want it to be and some of those that you just read are pretty large ticket items. I mean that's very broad, very broad.

JUDGE FADER: This whole thing is much, much bigger than I ever envisioned. I mean I can't believe --

MR. FRIEDMAN: And many of the states that are doing this are focusing on a controlled drug. I would also say if we decide to solely focus on controlled drugs, you might want to look at whether or not you want Schedule V included in there. Don, Schedule V doesn't even require prescription, right, I mean the patient can sign for terpenhydrate and codeine, right?

MR. TAYLOR: No, it does require a

prescription now.

JUDGE FADER: In Delaware, you can go to Delaware and buy Robitussin AC.

MR. FRIEDMAN: And you can still in the District buy four ounces of it. But what I'm saying is the tracking of that is different than using the pharmacy database.

DR. LYLES: Can I say something, if you don't mind?

JUDGE FADER: All right.

DR. LYLES: I think this is an aged group and you're aged from the point of view that you don't understand modern databases. The EMR systems already have what we're talking about. It exists already there. If we're going to do something at a state level, what we want is something that's functional along with an EMR system because that's where we're going. The people who don't have EMRs and aren't going to have it for the next couple of years, you'd like to give them some access to this, but that's going to be very limited access.

JUDGE FADER: Mary?

MS. ROCHEE: Good morning, Mary Rochee with DEA. I just wanted to ask the group here have we looked at what some of the other states are doing with respect to what drugs --

JUDGE FADER: Yes. Yes, there's a list that will be part of the report as to what other states do, what they don't do. A lot of it is the function of what it costs to do. What Bob is mentioning now is a lot of this is the developing database technology. David Sharp is going to tell you that in another five years Maryland is going to require every pharmacy to report every drug to the state of Maryland database. And we will have all of that information available.

MR. FRIEDMAN: So if every drug it going to be reported as part of the PMP program what do you envision --

JUDGE FADER: Well, not part of our program but as a part of the Bruce and David.

MR. FRIEDMAN: No, I understand that, but

what we're talking about here is we're trying to define what drugs and drug categories and there's discussion about having all drugs included. So if that's the case, who's going to be looking at those and what will they be looking for?

JUDGE FADER: Wait a minute now, just half a second now. That's going to be on page three.

MR. FRIEDMAN: Okay.

JUDGE FADER: Now, my old fifth grade teacher Sister Rita Gertrude said, Fader, you are a boy of limited ability, you do one, and then you go to two, and then you go to three.

Now look, here's what I have so far and primarily this whole project for the advisory council is for abuse and diversion, and the secondary aspect of it is for preserving to the physician the right to make judgments, but it's also a very, very important part of that.

So with that, I suggest we have three choices that I'll read to you now and then ask if anybody else wants to ask a fourth choice.

Choice number one is the recommendation we're supposed to make is II through V plus what the multidisciplinary body would do.

Choice two is II through V plus anti-anxiety drugs --

DR. FARAH: Mood-altering drugs.

JUDGE FADER: Well, you'll fill in the blanks. When you're coming out of your hospital bed, you can work on this, okay.

DR. FARAH: Well, whatever.

JUDGE FADER: Mood-altering drugs plus multidisciplinary.

And number three is all drugs period, okay.

Now I suggest that those are the three that I have down here now and would ask for comments, then I'd like to get the sense of what we're doing with this and then we'll write this up.

MS. KATZ: I have a question. Do we see this database as distinct from the database that we are projecting for the state as a whole?

JUDGE FADER: Well, we don't know. It's my humble opinion that if we can convince the legislature that the money is available to do this now, that the legislature is not going to wait for Bruce and David outside of the state funds. But if we can't convince the legislature of that now there's no money, so they will probably do a year or two of wait and see to see how Bruce and David are going. But that's just my personal belief. I have a feeling Bruce kind of agrees with me on that, but.

MR. KOZLOWSKI: Not really, but that's okay. This may be the only time that we disagree.

I think that just for 30 seconds here that to build a silo at this point in time would take almost as much to get it operational as getting the statewide system up and operational. And your investment in time and energy and the group meetings and everything else will in essence become obsolete at that juncture. So that's a consideration I have to make.

JUDGE FADER: One of the things that we're going to do is that we have had a number of states that have come on board, three to five states in the last couple of years. So we're going to Oklahoma and we're going to those states and we're going to say to them, you know, how much time did it take for you to get up and running so we have some of that information available.

Okay, so we're not going to go to the states like New York and Michigan that have been with it a long time, we're going to the more recent states to see.

MS. KUHN: I was going to say, I would think that you would want to do II through V and the multidisciplinary body, and I certainly respect why there's thought about the mood-altering or antipsychotic drugs, but I have again a practical, how the legislature works concern about that. There has been a lot of debate and certainly Dr. Lyles, you've come in and talked a lot about, you know, being very careful about what drugs we do

look at.

I think that we don't have, you know, the mental health professionals at this table and it's very likely they would come in to the legislature and say why all of the sudden are all of the people that we're putting on medication for depression being monitored. I understand what you're saying is that it's really is combination, but unless you specify that in statute, which is really getting into the weeds, I think you're going to run into a practical problem and so I do think you're better with those types of drugs coming in through the multidisciplinary body so you can be very specific in regulation about you're looking at those drugs in combination with other things.

It's very hard to do in statute, it's very difficult to draft, and I think it's difficult to get the legislature to understand that type of subject.

JUDGE FADER: This is a pretty sexy topic for the legislature, for the people getting ready

to go into an election year that has all the promise of anybody that's an incumbent gets thrown out. This could be a very, very brutal year.

DR. LYLES: I agree with some of your logic. I have difficulty with your thought concept when you use the word, monitored. Just because you have a database does not mean that the patient is monitored, it means that the data is available.

MS. KUHN: I agree.

DR. LYLES: This is the whole concept of a health information system is that this is available, not only for just law enforcement, which I have difficulty with if it's only for that, but for going past that and going into treating a public health problem with actual therapeutic treatment.

MS. KUHN: Well, I'm sorry, I don't mean to be misunderstood --

DR. LYLES: Okay, good.

MS. KUHN: I think that the point was aptly made earlier that really this, to me, is a

system where you look at it and it's what says, okay, I need to go find more information before I can make, if I'm a doctor, before I can make a determination if I've got someone in here doctor shopping. It's a starting point for one.

But, you know, there's been a lot of debate on this bill over the years in the legislature and what you constantly hear people come in and say is we're afraid we're going to be, we and our patients are going to be monitored, and I don't think we want to do that on the mental health side without having had the mental health professionals at the table to understand all the complexities that we're talking about. And because of that, I wouldn't put antipsychotics in the statutory language. I'd leave that for a multidisciplinary board.

MR. TAYLOR: I also think it's important to keep in mind that we want this database to be used, I've got patients, I can pull up a screen just for the last month and maybe on 19, 20

different drugs. That's two or three screens. Now, if I pull that for a period of three months, six months so I get a total picture, suddenly I've got a printout that's five to ten pages long of drugs, when they got them, how much, et cetera, et cetera.

I'm not sure that if you build a huge database for the purpose of just trying to do what I think the purpose of this work group is supposed to be doing, I think you're going to overload the system. It's not going to be used because it's just going to be too cumbersome for people.

Now the person that wants to treat the patient wants that information. The person that's going to be looking up this information just to see well, when is the last time they got it, did they go across the street and get it, he doesn't want all that information. He wants something that's concise, it's easy to use, that's fast.

DR. LYLES: That's precisely what we do not want in the medical profession.

MR. FRIEDMAN: And the EMR is much broader. That's a lot of opportunities for you. That's where the state's going to go then just looking at drug abuse.

JUDGE FADER: All right. Now I have to get to a point of cutting off debate on some of this, understanding there's so many preliminaries. And I have to also get to a point of emphasizing that those of you who feel strongly about one of these positions, as opposed to another, need to jump in here once we send this out to you because this is going to go out to you as to what you think, what you want added here and things of this sort so that they can see.

But can I cut off some debate now for a preliminary vote and say number one, II through V plus whatever the multidisciplinary people say, number two, II through V plus anxiety and mood-altering drugs plus multidisciplinary, and three, all drugs that are being taken.

DR. COHEN: Question, the anti-anxiety

drugs that we're concerned about are in the Schedules so that confuses me a little bit.

DR. FARAH: Yeah, that's right, that's why I was concerned.

JUDGE FADER: See, I didn't know.

DR. FARAH: Yeah, benzos are in the Schedule V.

JUDGE FADER: So are there any that are not in the Schedule?

DR. FARAH: But I was pointing out select medications that we know, like Depakote.

JUDGE FADER: So there's really only two? Number two is II through V, II through V. Bob, you agree with that, that II through V is also going to include the anti-anxiety drugs Prozac?

DR. FARAH: No, it's not. It's not.

JUDGE FADER: But somebody is saying that that could be important.

DR. LYLES: It could be because it's a serotonin problem.

DR. COHEN: But we're concerned about

diversion.

JUDGE FADER: All right. Mary, you have the last say and then we're going to take a preliminary vote.

MS. ROCHEE: I just wanted to add when we're looking at pushing through the legislation for prescription drug monitoring program forward, I think it's very important if we all think what is the intent of this legislation. Are we attempting to look at all the drugs or are there specific drugs we want to focus on?

JUDGE FADER: The intent of the legislation as stated on page one of the handout today, okay, is abuse and diversion, plus preserving to the medical practitioner the right and opportunity to treat the whole patient.

MS. ROCHEE: But I think if we are looking specifically at the goals of the prescription drug monitoring program is that to include the whole gamut of drugs in there? I believe it's very cumbersome and I think it's going to be a lot more

challenging to push the legislation forward. When you put it out for comments, you're going to have a much broader scale of comments.

JUDGE FADER: Okay. So again, I still have three, II through V, which is number one. Number two is II through V rather plus the Prozac and other drugs that Bob feels are there, and number three, all drugs. So can I ask for a --

DR. FARAH: Excuse me, Judge, just one second. There was an option you said II through V.

JUDGE FADER: II through V.

DR. FARAH: Plus a select through an advisory board, plus selecting a certain subset through an advisory program.

JUDGE FADER: That's number one.

DR. FARAH: That's number one, II through V plus a select.

JUDGE FADER: And number two is II through V plus Prozac, anti-anxiety and the group, and number three, all drugs.

All right, how about those who feel that

it should be restricted to II through V?

DR. FARAH: But plus --

JUDGE FADER: Plus multidisciplinary.

MS. KATZ: Plus the board, in other words.

JUDGE FADER: Twelve people, okay.

How about II through V plus the multidisciplinary and the anti-anxiety drugs, Prozac and things like that, plus the board?

None.

How about all drugs? One, okay.

All right, now, the last part of this is this, do we want that multidisciplinary body to have to go through the regulation process or just let the secretary make the appointment? In Maryland the secretary himself can make additions to schedule drugs without going through regulation. Any thoughts on any of that?

DR. FARAH: Can you repeat that? Because right now, for example our advisory board was set by legislation different slots for different representation. Now, that is one thing, and then

the advisory board to select or marshal the actual mechanics and day-to-day, it's a different group.

JUDGE FADER: It's a different group. But the question is, suppose that group makes a decision to add drugs to this, are you going to say that the secretary can then do that, accept that recommendation and make his own addition or do you want it to go through regulations?

Right now for Schedule II through Schedule V the Attorney General of the United States and John Colmers can add to that list. They don't need regulations, okay. If the advisory board, the multidisciplinary board makes a recommendation, do you want to say Colmers can then add that or do you want to require it go through regulation?

MS. KATZ: What if Colmers rejected the recommendation?

JUDGE FADER: Well, if Colmers rejects the recommendation there's not going to be any regulations because unless he approves it, you're not going to have regulations. The Board of

Pharmacy can't put regulations through itself. You're supposed to be able to by statute but if he says no, you can't really go against him, Don.

MR. TAYLOR: No.

MS. HERMAN: Why go through regulation?

DR. FARAH: Why go through the regulation? If right now the secretary has the veto power to cabash it no matter what you do so --

JUDGE FADER: Regulation is notice to allow everybody in the community that has a stake in it to appear in the Maryland Register and come in and say something about it.

DR. FARAH: But that's not going to happen by the word of the advisory group suggesting that.

MR. TAYLOR: Regulations take time. So you can get something added by the secretary or his agent very quickly. So if something suddenly pops up and we have Michael Jackson case, if something like that pops up and becomes a drug that we want to take notice of, it can be done overnight almost by the secretary doing it. If you go regulations,

minimum is going to be six months.

MR. KOZLOWSKI: Can I ask for clarification? I think the authority for the secretary has to do with Schedule drugs.

JUDGE FADER: It does.

MR. KOZLOWSKI: So we need to keep in mind that it has nothing to do with the thousands of other drugs that are out there which could be done regulatorily without a problem.

MR. TAYLOR: Actually, if it's a drug of interest he can still add it because they've done that in Maryland with specific drugs that are not Schedule drugs but in Maryland because it's been added, they are considered Schedule.

MR. KOZLOWSKI: But isn't that, I guess that's the good question is it has to sit in two parts. One is the authority of the secretary and later on how we want to deal with that.

JUDGE FADER: And you can also do it and say the secretary has the right to put it on and it shall be for six months or a year. It shall expire

unless a regulation takes effect. You can do all of those things, but the question is what do you want to do? Do you want to make a recommendation, and in my opinion the legislature's going to want to know what you feel about this.

MS. HERMAN: See, my concern is that things become sensationalized so that if there's a drug out there and all of the sudden people are against it, then the governor or somebody can come in and say, okay, we're just going to take this off the market right away. So that's what I'm concerned about.

JUDGE FADER: From the pain people's perspective you're saying you would be deprived of that?

MS. HERMAN: Yes.

JUDGE FADER: Okay.

DR. LYLES: At the DHMH we have a pharmacy therapeutics group that makes those decisions. It's probably equal among the pharmacists and the physicians, and I think they do a pretty good job

there for the most part. That can be done on a monthly basis.

JUDGE FADER: All right. Here's what I have so far, number one, has to be done by regulations only, number two, secretary, number three secretary for a period of time, say one year and expires without regulations.

Let me give it to you again. Regulations only, this is the multidisciplinary team adding. Number two, the secretary can do it on the advice of the multidisciplinary, or three, the secretary for a period of time, say a year and then that expires unless regulations are passed in that one year period of time.

MR. FRIEDMAN: Question though, if I understand what was said earlier, even if we were to vote for regulation the secretary still has the right --

JUDGE FADER: That's correct.

DR. FARAH: Only II to V. They said only II to V, not the others.

MR. FRIEDMAN: Only II through V?

DR. FARAH: That's what he said.

MR. KOZLOWSKI: Let's keep in mind, the secretary doesn't go off on their own to make these things. They get advice and consult. If anyone can hear of a time in which that authority has been abused, I think it would be helpful to speak up. It is not an authority that is used without great concern and great consult. So all I'm suggesting is let us not tie something up unnecessarily that the legislature has debated in the past by giving the secretary the authority to do this unnecessarily.

JUDGE FADER: What is that?

MR. KOZLOWSKI: I'm just saying that there ought to be another issue or another vote which says let it stay the way it currently is and then let's talk about all the other drugs in the context of the advisory group and regulation, et cetera.

JUDGE FADER: Does anyone disagree with me that we should make a comment on this one way or

the other?

MR. KOZLOWSKI: I agree with you.

MS. KUHN: But I think if I'm hearing Bruce correctly, I think what Bruce, and correct me if I'm wrong, may be suggesting is that because this law already exists giving the secretary this authority, maybe our comment is that we think in general it should go through the multidisciplinary committee on a regulatory process but we respect the fact that the secretary already has this authority in statute and may utilize it if necessary.

JUDGE FADER: That's part of the argument for or against but not part and parcel of number one, regulations only, number two, secretary, number three, secretary for a period of time of one year.

And of course what we're talking about is everything other than II through V because he already has the authority to add something to II through V. Okay.

How many people think it should be regulations only? One.

How many people think it should be the secretary by themselves?

How many people think it should be three, the secretary for a period of time, say one year and then expires without regulations? Now that can't be.

DR. FARAH: So number two is not the secretary by themselves?

JUDGE FADER: I'm sorry if I didn't make that clear, this is on advice.

Let me do this again. Adding a drug other than II through V to this list of drugs that would be put on here to have data submitted, you would say that the secretary, that it can only be done through regulations after multidisciplinary recommendations, that the secretary could do it himself after multidisciplinary, or three, the secretary could do it himself for a period of time, say a year, and that would expire unless

regulations are passed in that year.

MR. FRIEDMAN: And I want to get a clarification because I heard two different answers. Can the secretary only make decisions on Schedule drugs or on any drug?

JUDGE FADER: He can only make them on Schedule drugs. It has to be an habitual drug.

MR. TAYLOR: I still think he can make an addition of a drug of interest.

JUDGE FADER: No, I don't think that he can.

MR. TAYLOR: That's the way it was.

MR. FRIEDMAN: That's a big difference.

JUDGE FADER: Not unless it has addictive properties. It must come into the Schedule I, Schedule II, Schedule III criteria of the statute which means noted for abuse, two things, three things like that. He just couldn't put Prednisone on it, okay.

DR. LYLES: Let me ask you, how did you guys at the Pharmacy Board handle ephedrine when it

became a difficulty? I know it has to go behind the counter now.

MR. TAYLOR: Yeah, that was basically done by regulation and then they came out and actually passed a law on it, too. But initially it was done by regulation.

MR. FRIEDMAN: But it could be emergency regulations so it could be quicker than the standard regulatory process.

MR. TAYLOR: It was done as an emergency, yes.

MS. HART: Well, actually ephedrine was put behind the counter because of the act that the federal government passed and so that's why it's behind the counter.

JUDGE FADER: But they fit into the criteria.

MS. HART: Yes.

JUDGE FADER: Remember that statute both on the federal side and the state side has three criteria and that's for every Schedule. Number

one, recognized or not medical use, appropriate use. Two, subject to abuse. Three, the situation having to do with benefit to the society and the patient. Unless that comes within those three, which is number one, meaning that it's habit forming, subject to abuse, things of that sort, it can't go on.

All right, let me give it to you again. The multidisciplinary board makes a recommendation that something be added to the list of drugs for which data is to be submitted. Do we want then to say that can only be added number one, on regulations only, number two, with the secretary by himself, or three, the secretary for a period of time, say a year and then it expires without regulations enacted?

How many think it should only be through regulations?

DR. COHEN: So we're ruling out the one option of the secretary with an advisory board?

MS. KATZ: No, it's all with the advisory

board.

JUDGE FADER: It's all with the advisory board.

MS. KATZ: The advisory board takes action.

DR. FARAH: The advisory board comes up with a list, sends them to the secretary, he can either rule on it and we're happy and fine, or we can say he rules on it for that period of time and then it will be ratified by regulation, or it goes away.

JUDGE FADER: Okay. The advisory board makes a recommendation. They say you should add Prozac, or give me something else.

DR. LYLES: My example was ephedrine. How was that added.

JUDGE FADER: Okay, ephedrine. We should add this to the list then once that happens. Number one, it can only be added to the drugs for which data has to be submitted by regulation only. How many people feel that way? One.

By the secretary by himself only?

MR. TAYLOR: In addition with the board.

DR. FARAH: Yeah, the board.

JUDGE FADER: It's all in addition to the board, okay? Now wait a minute. Get those hands again --

DR. LYLES: What are we voting on?

JUDGE FADER: And then number three, by the secretary for a period of time, say one year and then it can only continue that way if regulations are passed.

DR. FARAH: Okay, now, let me ask a question, if that advisory committee picks up six medications that we feel are of great help for physicians and we put the necessary stuff that this is going to be mostly for physicians to help them take care of their patients, it's not going to be used for any other thing, whatever, there is money investment, time, effort to implement this and then the secretary says yes, and then about a year later after all this trouble has gone on, this is going

to stop. I think it's going to be a mechanical problematic issue.

JUDGE FADER: Who knows, everything is an issue, that's why we lawyers have so much work.

MS. EVERETT: And that's why number two works because you do all that, like you just said, and now unless somebody comes up and says yeah, we really want that, it goes away.

JUDGE FADER: I'm going to give it to you again, okay, because we have to cut these things off. You know, you can what if yourselves to death, all right. You can what if yourselves to death.

The multidisciplinary board makes a recommendation that something be added to the required database reporting by dispensers, okay. Then the question is, is that going to be added. How many people think it should only be added if there are regulations passed adding it? One.

How many people think that it should only be added if the secretary and just the secretary

approve it?

DR. LYLES: Just the secretary?

JUDGE FADER: Yeah.

DR. LYLES: The board, so you're talking about just the secretary?

JUDGE FADER: No, it came from the board.

MS. KATZ: It's all predicated on the board.

JUDGE FADER: It's all a predicate of the board. The board has to make a recommendation first.

DR. FARAH: Nothing gets to the secretary if the board has not decided that's what you do.

MS. KATZ: Can I ask, if the board makes this recommendation it would not take effect unless the secretary approved it? The board isn't empowered?

DR. FARAH: That's correct.

JUDGE FADER: That's correct.

And three, the board recommends it, the secretary can then put it on the list but it would

only be for a year and then it would come off the list unless the regulations were passed. Anybody go for that? No? Okay. All right.

MR. KOZLOWSKI: If I might --

JUDGE FADER: See, this is why in court they give a judge the authority to say I don't want to hear anything else, take it down to the appellate court.

MR. FRIEDMAN: If we go through the process number two is there an opportunity --

JUDGE FADER: I'm just going to put this on paper and send it out to everybody and see what happens with the comments.

MR. FRIEDMAN: That's fine, but I want to understand one thing as part of the process, is there an opportunity for public comment at any point during that?

JUDGE FADER: Not unless the secretary says there should be. I mean this is what Gwen is upset about.

MR. KOZLOWSKI: That's the advantage of

the regulatory process. And I just want to reinforce, and Linda, tell me if I'm incorrect, we file a regulation as an emergency and as standard regs simultaneously so the day we file it's in effect. Emergency regulation may in fact expire a month before my official final regs, that sometimes happens, but the truth of the matter is the process is a very, very good process.

And we get involved in really sticky wickets and it allows for public comment. We want everybody to have a chance for input. If you exclude them from that process, I'm just going to suggest that a legislative body, especially in a year of a reelection is going to be very sensitive to the fact that you're trying to do something without public input. And that doesn't ring well.

And I think I can just say this, having spent years in the regulatory process, it works and it works exceedingly well. And it precludes an awful lot of protests because people have had a chance to comment on the front end.

MR. FRIEDMAN: Exactly, I agree.

JUDGE FADER: All right. Now, question number two on page two, identify the types of dispensers that shall be required. I suggest that the answer to that question is all pharmacies, all physicians who dispense and it includes mail order people from out of state who come and sell in state.

MR. TAYLOR: I would only change the word physician to prescriber. It does not have to be a physician, just a prescriber.

JUDGE FADER: Any prescribers then?

MR. TAYLOR: Yes.

MR. FRIEDMAN: And I would change the word mail order pharmacy to nonresident pharmacy, or no?

JUDGE FADER: It says nonresident permit holder under the statute.

MR. FRIEDMAN: Right. I mean most of the board regulations --

MR. TAYLOR: Most of them are nonresident.

MR. FRIEDMAN: Exactly.

MR. TAYLOR: But we do have some that are in-state.

MR. FRIEDMAN: That are mail order?

MR. TAYLOR: That are mail order.

JUDGE FADER: Okay. All right. Now question number two, identify the types of dispensers. I would respectfully suggest the answer to that is all pharmacies, all prescribers who dispense and all nonresident permit holders. Anybody else want to add anything to that? Yes?

MS. EVERETT: Well, based on what you were just saying, do you want to also just say, and I'm not familiar if this is correct or not, and in-state mail order programs or something like that because you were saying there are some.

JUDGE FADER: Well, wouldn't they be a resident pharmacy?

MR. TAYLOR: They would be a pharmacy. Read number three again, please.

JUDGE FADER: All nonresident permit holders. You have two sets of regs.

MR. TAYLOR: You may want to say yes to the permit holders, you may want to say prescribers and dispensers, something there, but permit holder is very broad. I'm not sure that all permit holders would be appropriate. What you want is people who are prescribing and dispensing into Maryland.

JUDGE FADER: Well, I never thought of it before, I guess there are physicians in York who dispense for Maryland.

MR. TAYLOR: Definitely.

JUDGE FADER: Okay. Well, wouldn't they have to receive a permit to dispense?

MR. TAYLOR: In general they're regulated by the state they're licensed in.

DR. FARAH: The irony is for example, in Delaware they will not give me a license there because they say I don't have an office in Delaware and so from Maryland I can dispense in Delaware without being scrutinized by Delaware. And I tried to talk with them, I said wait a minute, this is

counterintuitive.

JUDGE FADER: Now, LaRai, we're going to have to look into that because I think that constitutionally, and I'm not up on this, I'd have to ask Bill Reynolds or somebody who's a constitutional lawyer down at the law school. The reason that we can regulate nonresident pharmacies is because they come in through the mail, right Mary?

MS. ROCHEE: Yes, and I would say that in any of these states with prescription monitoring programs they generally have from their legislation anyone who causes drugs to be delivered in the state. And so if you have a doctor who's prescribing to patients who bring their prescriptions into Maryland to be filled, their prescriptions will end up in that prescription data for Maryland.

And I have a comment for types of dispensers. You said all prescribers who dispense, I think you could just say all prescribers, just

because they dispense, what about those that prescribe.

JUDGE FADER: All right. Let me put some questions there and then we can work on all of that, but aren't we pretty much in agreement that we want to catch anybody and everybody that we constitutionally can who is out of state and treating people from Maryland?

MR. FRIEDMAN: Did you say all pharmacists?

JUDGE FADER: All pharmacists.

MR. TAYLOR: The one thing you do not catch with pharmacies are your in-patient pharmacies and your institutional.

MR. FRIEDMAN: Nursing facilities.

JUDGE FADER: It does catch in-patient pharmacies, the 2006 bill specifically excluded in-patient hospital pharmacies but --

MR. TAYLOR: Yeah, the ones that deal with the outside. You probably want to exempt some localities, your institutional, your in-patient

institutional where the drugs are not getting out.

JUDGE FADER: All right. Let me put institutional, question, Don, okay. We'll put this up and see what's going to happen.

MR. FRIEDMAN: Are you going to have exemptions, reporting exemptions?

JUDGE FADER: No, there will be no reporting exemptions in the other bill, the 2006 bill except in-patient hospital pharmacies.

DR. LYLES: And that means if they are discharged, if they get a selection of medications they become outpatient and so they have to be monitored.

MR. KOZLOWSKI: The outpatients should be monitored.

DR. LYLES: Yes, definitely.

MR. KOZLOWSKI: And I don't know, I'm not familiar with all the nursing homes here, but I know the nursing homes have raised the concern that they be excluded from this because they don't dispense to the outside. They may have a pharmacy

on site.

DR. LYLES: They administer.

MR. KOZLOWSKI: Right.

MR. TAYLOR: And that will come up because they will ask to be exempt.

MR. KOZLOWSKI: There's no question.

MR. TAYLOR: Yeah.

MR. FRIEDMAN: How about dispensing to patients of hospice?

MR. TAYLOR: My personal feeling is it probably should be reported, but that's just my personal feeling on that.

JUDGE FADER: All right, let me put that. You're a tough crew. All right, data that would be submitted. Here is the 2006 bill. Now in the 2006 bill it's got all of this data through the multidisciplinary team.

The question is, do we want to say the multidisciplinary team controls that or do we want to specifically say patient identifier, Rx dispensed, date of dispensing, quantity dispensed,

prescriber, and the pharmacist?

MR. TAYLOR: I would prefer to leave it up to the multidisciplinary team to make a decision as to what data they want included in the database instead of trying to itemize every single thing. Once it's in there, it's not easily changed, right?

JUDGE FADER: All right. Question number one, leave it to multidisciplinary team, two, specify in statute.

All right, how about number one, leave it to the multidisciplinary team, how many people feel it should be that way?

How many people feel that the statute should specifically state what data is to be collected? Okay.

All right, now the directive of the statute in the 2006 bill is that all data is to be selected electronically unless there is an alternative dispensing or exemption made. Do you want to put that provision in the statute?

We came back from this conference and it was said at the conference that most states have that, that they do have some exemptions for little ma and pa pharmacies that's out in Garrett County somewhere in the side streets and all that, that doesn't do it. But the statute itself requires that it be submitted electronically unless there is an exemption. What do you want to do about that?

DR. FARAH: And the question is who's going to give that exemption?

JUDGE FADER: Well, yeah, okay.

MS. KATZ: So in other words, we're saying that for that non-hooked up pharmacy it would be by fax? They would have to submit?

MR. FRIEDMAN: No, there's different ways they can do it. They can submit a report, a hard copy report, or they could upload the information onto a web based system. I mean Virginia has like four or five different ways that they can do it.

DR. LYLES: There's no one in Maryland that can't do it electronically.

DR. FARAH: Yeah, I have a problem with non-electronic means. I really do because who's going to enter the data, who's going to check it? There is an error introduced by the second step by mistakes which could be devastating. You can't backtrack with that individual.

There was one situation where the same doctor was given all of it because it was much easier for the person to put the same doctor. So no exemption.

MS. KATZ: And I think that this was written in '06 and we're talking about implementation in 2011.

JUDGE FADER: Well, but we still at that conference heard that all of these states make exemptions and allow an exemption to be made and there still are people out there.

So the question is what do you want to do about this? I mean I can tell you that the delegates from New Windsor and places like that are going to say this stinks, we don't know how to use

computers, we're 76 years old and I don't like computers.

MR. KOZLOWSKI: How about an option to grant if the advisory committee and the secretary is the final authority on that so they could make a request for exemption to the advisory group and the secretary would be the determining factor in that exemption?

JUDGE FADER: Well, that could be it, but I kind of think if there's going to be an exemption the secretary ought to be able to grant it himself, but that's up to you, whatever you want to do.

MR. KOZLOWSKI: That part's fine, too.

JUDGE FADER: Okay.

MR. TAYLOR: I know West Virginia has an exemption. They had to hire two staff people to do the data entry. They have since taken away that exemption because it was just too cumbersome, it was too hard to deal with. And as of now in West Virginia, I think I was just told they only have three pharmacies in the state that cannot submit

electronically.

MS. ROCHEE: I was going to say in DEA we've switched over most of our processes, even our registration process electronically. And the Federal Paper Reduction Act, we still must make an allowance for people for whatever reason who have not been geared up for electronic.

JUDGE FADER: In this situation do we say that the statute should contain a statement that data must be submitted electronically unless an exemption is granted by the secretary? All in favor of that? All against? All right.

Specify recipients on page three authorized to receive prescription drug monitoring from a prescription drug monitoring program, identify the circumstances.

Okay, the 2006 bill talked about who these people were, a dispenser, a prescriber, federal law enforcement agency, state or local agencies, a licensing entity, the Maryland medical and pharmaceutical assistance programs.

I don't know what they would need it for, but you know, the physicians it would seem to me that are prescribing would need that, but a patient with respect to information about the patient or any other contract with the department concerning the operation of the program. Page 11 of the 2006 bill, and when I say page 11, it's my page 11 here. Everybody understand that? Okay.

Regulations to identify the circumstances under which monitoring data is to be provided to an authorized recipient, page 11, ensure the program designed to receive data in a manner compatible with existing submission practice of dispensers.

Now, it appears to me that there are, this is a hot ticket item, okay. Questions, when and under what circumstances are law enforcement personnel going to have access to this. The law enforcement personnel have agreed pretty much that this would not be a primary source but would only be a secondary source when probable cause existed for an investigation. Right, Mary?

MS. ROCHEE: Pretty much, yes.

JUDGE FADER: Pretty much. What else do you want add to that?

MS. ROCHEE: I think there are some instances when, I know in Virginia there must be an active investigation or some other major reason why we need to be looking at that information. We don't look that up just arbitrarily. We don't have that type of access.

JUDGE FADER: I would put my law assistant to go to Virginia, you tell me what other states, to see what their statutes say is the condition, precedent for law enforcement there. Yes?

MS. EVERETT: That is what the agent or the trooper from the Virginia State Police stated that --

JUDGE FADER: Active investigation.

MS. EVERETT: Only through open investigation do they actually look into what is provided by the prescription drug monitoring program.

MS. ZOLTANI: He said there must be a subpoena.

MS. KATZ: But he also said that there were only ten of them that had that access.

MS. EVERETT: Right. Agents in a small group, a specially trained unit that was specified to control or have access to that data.

DR. LYLES: There have been some very egregious situations in Virginia.

MS. ROCHEE: I can say also that when --

JUDGE FADER: Mary, you know we love you.

MS. ROCHEE: I know you do.

JUDGE FADER: But my God, I can't hear you.

MS. ROCHEE: Well, it's just food for thought.

JUDGE FADER: I know, but you've got to speak up. Can't you see how old I am?

MS. ROCHEE: Okay. Just that I know there's been instances where we may have an investigation that is maybe even focused on a

target that is out of our jurisdiction, okay, it could be someone in California. But we find out that that particular target, say we have an Internet pharmacy, for instance, that's shipping drugs into a certain state and we will want to look at that particular pharmacy's prescription drug monitoring information to see how many prescriptions are being dispensed from California, and we have an investigation but it's not focusing specifically on that pharmacy in Maryland, okay.

I want to just make that clear because sometimes I think it's perceived that we have to have an investigation on a particular pharmacy as a result of our enquiry, but it may not be focused on that particular pharmacy. It's just something, a corroborative tool, okay.

JUDGE FADER: All right. Bob, you were saying there have been egregious situations in Virginia. What can you tell us about that?

DR. LYLES: That if the patient down there, we had one situation where the patient was

arrested for drug dealing, said I got this from a physician. When I reviewed the case, the physician had prescribed appropriately for this person and had no idea that they were doctor shopping, per se. The board went after this physician. And hearing Ramsay and I talk about documentation, this was more a documentation case than it was a prescribing situation that was incorrect. But he doesn't have a license now.

MS. EVERETT: But that's the board, that's not law enforcement.

DR. LYLES: That is law enforcement. The board is law enforcement.

MS. EVERETT: That's different from like the DEA or the state's attorney office.

DR. LYLES: No, they knock down doors just like you guys do.

MS. EVERETT: I guess I'm looking at law enforcement --

MS. KUHN: The 2006 bill lists both of those types of law enforcement.

JUDGE FADER: All right, John?

MR. MOONEY: I can tell you that the Maryland State Police is not interested in being a clearinghouse as the Virginia State Police is. You know, Virginia had, I think ten investigators where all cases had to go through those ten investigators. The state police at this point does not have the manpower to do that. We are 22 investigators down within my division. I'm not capable at this point of assisting on every diversion case throughout the state. There's got to be some other control on how law enforcement would get to the information, other than coming directly through the state police.

DR. FARAH: I know we've referred cases to you.

MR. MOONEY: Right. We do diversion cases, not that often anymore. We do not have a diversion unit. We do work diversion cases, but it's not a majority of our work.

DR. FARAH: I feel the type of access

should be a routed access not a direct access. I feel this is the kind of area where if there's an actual court subpoena by a judge, it's one thing. If there's no subpoena by a judge for a good reason because they would have that good reason, it should go through the committee. It's called an advisory committee, they should review it.

JUDGE FADER: See, you can't do that constitutionally, you cannot interfere with the right of the Attorney General of the state of Maryland who kind of tells Mary what to do, and the right of a prosecutor, you cannot constitutionally interfere with their rights to investigate crimes, because it's stated in the constitution that it's there. It's just not going to work, Ramsay, that constitutional protection.

DR. FARAH: Well, can you tell me from this constitutional protection concept how, for example, the state of Vermont law enforcement has absolutely no access?

JUDGE FADER: I have no idea what their

constitution reads. I do know this, that our legislature has made a specific exemption for law enforcement personnel to get to medical records in the state of Maryland. Law enforcement personnel cannot get at psychiatric records in the state of Maryland. There is a case now before the Board of Appeals that they've been sitting on for two years.

DR. FARAH: I know all about it.

JUDGE FADER: Concerned about whether or not the board can have access to psychiatric records. And we don't know what the answer to that is going to be.

DR. LYLES: Well, let me give you a practical point here --

JUDGE FADER: If LaRai was doing an investigation on me, and she wanted my psychiatric records, she couldn't get them.

DR. LYLES: If we can't solve this here, this bill is going nowhere. This will die. We might as well just disband the group today and go home and enjoy the kids.

JUDGE FADER: We that you understand.

DR. LYLES: It's got to be resolved.

JUDGE FADER: It's got to be resolved.

DR. LYLES: Yes.

MR. MOONEY: Judge, couldn't the data be similar to the criminal justice information system where every time one of my investigators logs into the system, it is monitoring who logged in, what they looked at, and that way it'll be a way to track who's going into the system and do they really have a purpose for going into the system.

Every once in a while, I'm not sure of the time frame, but investigators are given a list of all the names that they've queried and they have got to pretty much prove that they were doing an investigation to go in and get somebody's criminal record. I don't think the legislature is going to go in Maryland to allowing every policeman to get in. I think that each state's attorney's office, the DEA, drug control is going to have to designate a single individual to do that or the legislature

is never going to go through with it.

Now, I don't know how that's going to work out and perhaps that would be for the multidisciplinary team to decide. But at the same time, unless we come up with something in the statute as far as a legislative enactment, Bob's right, we might as well go home.

DR. FARAH: Well, maybe that the team would be inducted as employees of the law enforcement system. I don't know how that's done.

JUDGE FADER: They're not going to let everybody, everybody who's a member of the board of physicians. They're only going to allow certain people there that can access. Now, that does not mean that they can't share that with the board of physicians, it just means that the access is going to be limited.

DR. LYLES: It just comes down to does the patient have access to this data?

DR. FARAH: Well, my feeling the patients should have access --

JUDGE FADER: Wait a minute now, just a second.

DR. FARAH: Sorry.

JUDGE FADER: That's the next topic.

DR. FARAH: All right, we'll talk about that later.

JUDGE FADER: You're killing me.

DR. FARAH: Sorry, I don't want to jump.

JUDGE FADER: Remember Sister Rita Gertrude? That is a true story, all right.

DR. FARAH: Now, I really feel this would be a safety valve, a filter, a committee that is going to process this, unless there is a subpoena. If they feel strongly, let them get a judge to subpoena so there is no tampering. Because in the system there is a way to do it, get a judge to say yes, you need to access it.

JUDGE FADER: Now, the way right now, you cannot get any financial data, she can't get any hospital data or anything like that. She can get me to waive not telling the person that they're

coming in for the data, but unless I sign something that says they can get in, they can't get in. She can't get any of that information.

MS. EVERETT: Well, I think I read, I'd have to go back, but I think in some of the other states it was specifying exactly what you're saying, Judge.

JUDGE FADER: Well, I'll get John Stamp (phonetic) to go through there and find that all out.

MS. EVERETT: I think that's how the access, along with the fact that there was an open investigation or an active investigation, not just an arbitrary let's check this doctor out or pharmacist out, there's some reason. And then a court order, subpoena was required, I think. I'd have to look, but I think that's the way they do it.

JUDGE FADER: Well, I'll gather information from a couple of states.

MS. KATZ: Yeah, that's the thing that in

the Virginia presentation that really bothered me that the phrasing was an active investigation or an open investigation. To me, it would possibly be very easy to open an investigation, but having the threshold of a subpoena makes it much more meaningful and much more structured and gives me a greater sense of security.

MS. EVERETT: Right, but the reason you're going to get that court order or subpoena is based on an active investigation.

MS. KATZ: Right, but one that has progressed beyond there was a telephone call that said I think so and so is dispensing drugs.

DR. FARAH: I think a higher bar of credibility.

MS. KATZ: Yes.

DR. FARAH: Of substance, because that judge is going to look at it and say, you know --

MS. EVERETT: And also on my review, we had received a packet, and I'll bring it next time for the rest of the group, law enforcement was like

on the bottom of what was reviewing all of this information, like the percentage was so low in comparison to every other entity.

JUDGE FADER: Well, that's where the legislature is going to want it.

MS. EVERETT: I know, but I'm just saying, just in general that we are, law enforcement is the lower end of the spectrum of people that are accessing it, not that we don't have to put the necessary things in place to ensure who has access and doesn't, but just so we know.

MS. ROCHEE: I think also when we have an open investigation in DEA, we have pretty much a straightforward format that we have to support a basis for issuing an investigation. Someone can't call on the phone and open an investigation. We're required to check out the facts and have supporting facts to have an investigation.

JUDGE FADER: All right, let me read you what the statute says with regard to medical records with regard to confidentiality and law

enforcement, subject to the additional limitations for mental health records which are very, very strict, okay.

To grand juries, prosecution agencies, law enforcement agencies or their agents or employees to further an investigation or prosecution pursuant to a subpoena, warrant or court order for the sole purposes of investigating and prosecuting criminal activity provided that the prosecution agencies and law enforcement agencies have written procedures to protect the confidentiality of the record. That's health, general, Title 4-306. So let's take that out, I'm going to insert that in here.

MR. MOONEY: I don't see anything wrong with it. We have to get a subpoena for phone records so why wouldn't we get it for medical records.

JUDGE FADER: Yeah, you have to come to me for phone, for medical, for financial records, you have to come for health records.

MS. EVERETT: Pretty much everything.

JUDGE FADER: Pretty much everything.

MR. MOONEY: It'll stop the fishing. The concern is the fishing.

MS. EVERETT: That's right.

JUDGE FADER: And I can tell you, I used to send those things back, particularly phone records because I'd say to the cops, the reason you give here is this is a nice thing to do. I don't buy that, why? And then they would have to come back and say what kind of an investigation they were doing. All of those things were locked up in a cabinet downstairs.

But, you know, with all due respect to you, John, some of these police officers come in, state's attorneys know better, but they would come in and they would ask for all sorts of things pursuant to an investigation, without telling me what the investigation would be, and I would say, no, no, no, no.

DR. FARAH: Well, then as far as health records you're only going to give the minimum you

need to serve the purpose of what you're supposed to be giving. You're going to have to watch for the privacy.

JUDGE FADER: Here's what I have for this, we'll send this out to each of you and I will be sending something out to each of you with regard to these first ones in a couple of days for comments, corrections, things of this sort. We'll put the healthcare thing in here.

LaRai is going to call me on Wednesday with what she feels she recalled from one or two other statutes, right, LaRai?

MS. EVERETT: Yes, sir.

JUDGE FADER: Yes, sir, okay. And then I'll have John Stamp also see from some of those other statutes what he found and we'll put all of this in here.

Let me skip down then to patient access. In my opinion the patient should have access but it should be like the confidentiality of medical records, which means if they say no, I want a

correction, we don't correct anything, we just put in the records patient says this is incorrect and the correct thing should be.

Okay, anybody else think anything else should be applicable to that?

DR. FARAH: Well, I think the patient should not be licensed to go into the system and query the data directly.

JUDGE FADER: No.

DR. FARAH: He can only get what his doctor prints out for him or his pharmacist prints out for him. It has to come through the certified authenticated accessee through the system.

JUDGE FADER: In other words, if a physician has accessed it --

DR. FARAH: Then he can give a copy to him.

JUDGE FADER: Then he can give a copy to hi patient.

DR. LYLES: And I think that whole concept is changing though.

MR. KOZLOWSKI: Very much so.

DR. LYLES: Yeah, and that's not going to fly in the future.

DR. FARAH: I understand, but to credential, to go through the safety of credentialing an individual that can hack into his next door neighbor, his ex-spouse, however they want to use it for divorce issues and so forth. It's a nightmare and I cannot credential 50 million.

JUDGE FADER: Well, wait a minute now, the patient can only get his own records.

DR. FARAH: That's what I'm saying.

JUDGE FADER: There's no question. I tell my pharmacists all the time they come in and say, I want my husbands medical records. No. But I'm married to him, I sleep with him, I feed him. No.

DR. FARAH: And the thing is if somebody can access somebody else because --

JUDGE FADER: It happens all the time in divorce cases.

DR. FARAH: And right now it's a criminal thing but logistically you cannot credential 50 million people to be able to have access.

MR. FRIEDMAN: Let me ask you this, if you're comfortable with a patient because the physician has access to the system, getting access to their own records, a pharmacist has access to the system, are you comfortable with a pharmacist giving patients access to the records?

In Virginia, neither the physician nor the pharmacist can give the patient access to their records. The patient has to request data on themselves through the prescription monitoring program.

JUDGE FADER: All right, now let me just stop you there. In Maryland, we already have a Confidentiality of Medical Records Act that enables a patient to come in to CVS Pharmacy and to say that I want a copy of all my records, period. They have to be given to that patient.

MR. FRIEDMAN: But those are the records

of the drugs dispensed by CVS, correct?

JUDGE FADER: That's correct.

MR. FRIEDMAN: But we're giving the records of anything on that patient from any pharmacy in or outside the state as part of this program, right?

JUDGE FADER: Okay, but I'm just telling you what the Medical Records Act. They can also go over to Walgreens, they can also go to Ramsay and they can say, I want all the records that you have on me and he has to give them to them, okay.

MR. FRIEDMAN: Right.

JUDGE FADER: So that's what we have in place. Now the question is what do you want to do about this?

DR. LYLES: Well, the present situation with EMRs and Sure Scripts is I have the last two years of records of every prescription that is not basically self-pay or being excluded. The patient has a right to that because it's in their medical record and I have, what, 21 days to supply it to

them or something like that.

DR. FARAH: But I have a problem with the patient directly accessing the system.

DR. LYLES: They have access. They have a portal that they can come in and look at their healthcare record, including their last two years of pharmacy and they can potentially print this out at home for themselves using a password and a PIN number. Now, how do you protect passwords and PIN numbers?

JUDGE FADER: Boy, that's dangerous.

DR. LYLES: This is the standard that's in the community now and this is going to be the standard that we're probably going to see because all of the vendors have this.

JUDGE FADER: Yeah, that scares the hell out of me, having tried 10,000 divorce cases over 26 years.

DR. LYLES: They have PIN numbers, you know.

JUDGE FADER: Yeah, I understand all of

that but that scares the devil out of me. This year already I have denied, I know 25 to 30 requests for a husband or a wife for the access of their medical records to a physician or a pharmacy. You know, you just can't do that. I know it's 25 or 30 so far, the motion has come to me for a protective order to quash a subpoena and I've granted every one of them.

MR. FRIEDMAN: Not every physician or pharmacist everybody has to be part, not everybody may choose to sign up for access to this system, so would it be voluntary for the pharmacist?

JUDGE FADER: That's up to you. I wouldn't give a patient access to a system with a PIN number or anything.

MS. KATZ: But I think what Alan is saying is that if my physician reported my drugs but had chosen not, which obviously they had to be reported through the regular system, but my physician chose not to have access to the system, didn't want it, didn't think he was going to need it, then where

does that leave me, you know, how do I get access?

MR. FRIEDMAN: Correct. And in the pharmacy you might have ten pharmacists in at any given time or shift and if a patient comes in and says I want to access to my records, the pharmacist may not be a registered user.

MS. KATZ: What if Kaiser Permanente decides corporately that they don't want Alan to have access, so then all Kaiser members would essentially be shut out.

JUDGE FADER: They can't do that because this law controls it.

MR. MOONEY: Judge, what if it was like a criminal record, individuals can apply to get a copy of their criminal record. You have to pay a fee, which would help offset the employee doing it, but they can get their criminal record or their medical record when they identify who they are.

JUDGE FADER: It's the same thing.

MR. MOONEY: Right. And then I can look their criminal record up but I cannot

re-disseminate it.

JUDGE FADER: You can pull the criminal record up if you have a reason to pull the criminal record up.

MR. MOONEY: Right, right, but I can't re-disseminate to the individual.

JUDGE FADER: My secretary can sit at her desk and she can pull those things up but only if I had a reason to. When they put all those systems in they came in and they made sure and they told her, Ann, you can't do this for your neighbors, as much as you would want to. And you know how many times I went into that? None. She was the one that was authorized to go into it.

All right, Don, come on, what do you want to say about this?

MR. TAYLOR: I don't know, patient access is iffy because there's just so many things that can go wrong by allowing patient access. I also have problems with allowing a pharmacist to give out the patient record. I think it has to be only

like we do now with the signed consent. It has to be in person, the whole works. It can't be mail, it can't be anything else. It has to be given to them in person. I think that existing conditions are perhaps adequate, but they have to be strongly enforced.

JUDGE FADER: Now, I agree with Bob Lyles that the state of art that is coming is for access for everyone to have access to everything with a PIN number or a thumbprint or whatever, but my answer to him is, let's wait until we have to do that.

MR. KOZLOWSKI: Well, technically we have to do it now because you have the right for personal health records and those health records are stored in a less than optimum way, at times in silos off site. So that technology is there and the right to put the data is there and it will continue to be there. Most of the data except for the personal health record there are other accesses to your personal database or your personal health

records on a view-only basis without the ability to print.

But when you elect as a consumer to put it into a separate health record or personal health record file, then you can do whatever you want to with it, that would be always separate and distinct from anything that the state was involved in. Once you make that election, you assume all the risks and the liabilities for doing that.

And with the recognition that physicians for the most part about 100 percent would never accept documentation out of your personal health record, they would go back to the main data source and that's where they would extract data for purposes of making a clinical decision.

JUDGE FADER: And here's something else that's going to come up with this thing too with what Don is saying. Don is saying that we make them come in and we make them have a written consent, we make them show their driver's license or identification. I tell my students to do all of

that.

But how about the situation where somebody's bedridden, they can't get into the hospital, to the pharmacy, the question there is can you take a request over the telephone and mail it, mail the record to that person at that particular address? The post office says it's a crime for anybody else to open that envelope.

So that is a real question and I do tell my students only in the most unusual of all circumstances that you are familiar with this patient, you can check that this patient is bedridden, they can't get in here or something of that sort. Because you know, you can even mail them out the consent form and somebody else can sign the consent form. You say, well we're going to have it notarized, well, how can I get out to get something notarized.

All of those things, and don't you think this legislature is not going to want to protect people who are too poor? Okay, so all of those

things are problems, too.

DR. LYLES: With us it's been recommended that to get the records you have to have a power of attorney.

JUDGE FADER: It says you have to have a power of attorney but the question is what are those powers of attorneys, do they have to be in the state of Maryland notarized? I mean I tell my students that if it's signed and somebody's there if it's notarized, fine. If it's not, then if it's an attorney that has signed and witnessed it, you call that attorney up and make sure that the attorney says that they have witnessed it.

And this is only going to happen once every four, five, six months. This is not going to happen that often, but when it happens, I tell the students don't trust anyone, okay.

And the question is that I don't know what the board of pharmacists is going to do about that, but at the same time it just seems to me that there are going to be occasions when those records have

to be mailed, but not very often.

MR. FRIEDMAN: I want to understand something you said earlier. Every physician who dispenses and every pharmacy that dispenses will be sending records into the system?

JUDGE FADER: Right.

MR. FRIEDMAN: You were saying though that every physician, regardless of whether they're dispensing or not, and every pharmacist will be required to have access to the system.

JUDGE FADER: If they qualify, yeah, and 99 percent of them are going to qualify.

DR. LYLES: I think it's pretty well laid out in the HIPAA section 164, you know, we use this all the time.

DR. FARAH: You can a lot of physicians don't want to access that. They don't won't to deal with that.

DR. LYLES: Section 164 kind of addresses all of the concerns you're talking about.

JUDGE FADER: Yeah, well the problem with

that, Bob, is that $20,000 later with a legal bill you can find that you've done nothing wrong. And what Ramsay's saying if physicians don't register to have access to the system, then they don't have to worry about paying a $20,000 legal bill when someone sues them.

DR. LYLES: And that's the difficulty with access to avoid criticism.

MR. FRIEDMAN: And so if everybody has access and upon demand or request by the patient to get their records would the safeguards about proving identity and signing a release form be in the regulations or is that up the individual physician?

JUDGE FADER: This is all in the Confidentiality of Medical Records Act. It works well. My suggestion is we consider just adopting that and my suggestion to you is that we also adopt the fact that a patient who yells and screams that this isn't correct, that Dr. Lyles has not stated this correctly, has the right to have that noted on

their record, but the pharmacist and the physician cannot change that record. So that's my suggestion to you.

A comment from behind the pole?

MR. WADJA: You can't see me, Judge, I'd like to go back to a statement that was made earlier and sort of relieve Don and Bob of the gatekeeping responsibility of getting this information for the patient. It really shouldn't be the program. If they've presented documentation, and photo IDs and all this, they're the data keepers, why would you want to burden pharmacists and physicians in doing this. This is just another layer of liability for them, I think.

DR. LYLES: Yes.

MR. KOZLOWSKI: The data's not sitting in a can someplace, the data's sitting in a physician's office, in a pharmacy, in 300,000 other places. The system knows where every piece of data is, and when it needs it, it goes out and gets it and gives it to the seeker or the person making the request.

So we're not, conceptually we're not building a silo in which data is coming into a silo, we're building a system that says I know where everything is and if you ask for it, I'll get it for you.

JUDGE FADER: All right. Let me ask you a question --

MR. WADJA: But still the program operators would have access to that.

JUDGE FADER: All right, but Bob, when you get access to that information can you print it out?

DR. LYLES: No, it's not print, it's read only.

JUDGE FADER: It's read only?

DR. LYLES: Yeah, I take my laptop over to the patient and I say, look, you've already filled this prescription.

JUDGE FADER: Well, if it's read only and it's going to be read only by the physician, they don't have any records to give the patient anyhow.

MS. KUHN: But then they also can add an

addendum if the patient has a disagreement, right?

DR. LYLES: You can read it, you can't change the data. I can put it in the medical record.

MS. KUHN: Oh, in your medical record but not in the database? Okay.

JUDGE FADER: So isn't the answer that if a patient wants this, they have to come to the secretary and ask for this because the physician doesn't have a record and the pharmacist doesn't have a record.

DR. LYLES: Only if you make it read only.

JUDGE FADER: Okay.

MR. TAYLOR: In the pharmacy it is not read only at this point. Existing databases, anything that we have for a patient is printable. So if you make it read only, that's fine.

JUDGE FADER: Well, that's another question and we'll have to find out what the other states do.

Now, did you everybody agree that if

whatever we do with this, making it available, making an application, that if a patient disagrees with the information that statutorily as they have in the health records of the patient, the pharmacy or the physician in the program would not be able to change it, they would just be able to register? Everybody agree with that pretty much?

MS. KUHN: Yes, but I would add that I think what Bob was saying that because he was read only, his notation about a change is in his patient's medical record, not in the database, so making the database read only ties into that question of having an addendum.

DR. FARAH: We need to address that because one of the most common things is if a prescription pad gets stolen and they have the same doctor's name on about, you know, 20 different prescriptions, then the database is saying that this guy has written all of these things and there is no way to correct that, so you really need to take that into account. That happens.

JUDGE FADER: Sure.

DR. FARAH: I mean it happened to me and the reason I went to court was to testify that I didn't write that prescription. So no, I didn't see this guy, he's not a patient of mine. I didn't write this, it's not my handwriting. So I have to go and do that physically because my nurse stole my pad and sold it. And of course she got prosecuted, but meanwhile you have 20, 30 people writing with my prescription. So we need to correct this kind of thing.

JUDGE FADER: Well, this is another situation too with regard to the medical society, that every pharmacist can tell you stories about how they've tried to contact physicians to corroborate the fact that this has been written and they're not allowed to get through. And the situation is they can also tell you of one or two instances where the girls up front were running a situation for their patients and things of that sort.

Don, you have certainly seen your share of that. My wife has said that she would, you know, call the physician and say you tell him I want to talk to him and insist upon it, and one of the physicians came in and paged through his prescriptions that he was supposed to have written and he said he didn't write it. So he went back and fired everybody in the office.

But those things happen and physicians need to know they have to give access to the pharmacies, not just to the secretaries and people when the pharmacist has a real problem. You see much of that?

MR. TAYLOR: A lot more than I'd like to see, yes. And in general, it's a trusted employee that's been there for years, runs the whole office, doctors trust her or him for everything that's going on and just doesn't question it, signs off at the end of the day, everything's fine.

JUDGE FADER: All right. Here is a heart stopper. I don't know about the rest of you, but I

think we're doing pretty good, and between now and next month when we come back with the rest of this stuff, we'll flesh out this and send point by point. Nothing is going to be sent to you in a group, everything is going to be sent individually. In other words, the first thing that we'll send you is finding out what other states do about the program, adding what they add, whether it's the multidisciplinary team and things and printing out what our recommendation is.

And then the second thing that will come out to you will be dispensers, you know, who people say they are, the definitions and things, and we'll get one or two of these things out to you every week, of the stuff that we're talking about.

And then we'll ask for your comments to be sent to Georgette. And comments can be sent to her, sent to anybody. If you want to ride past her house and wrap a piece of paper around a brick, throw it in the window, she'll take that.

All right, here it is, determine how to

ensure that confidential or privileged patient information is kept confidential. The legislature wans a recommendation on this.

Alan, what's your suggestion?

MR. FRIEDMAN: I'm going to pass on this one.

JUDGE FADER: All right, Bruce, why don't you tell us what's happening?

MR. KOZLOWSKI: Let me just read a paragraph for you out of the document that you all have. And regrettably David's not here today.

JUDGE FADER: Can you tell us what that document is, please?

MR. KOZLOWSKI: Yes, it's the one that we passed out earlier today that looks like this. The title on this is technology to support a prescription drug monitoring program, and if you go to page 8 under privacy, it's very telling and as David puts it, and I wish he was here because he could give explicit intimate details, in some areas Maryland privacy laws are more stringent that HIPAA

requirements.

JUDGE FADER: They certainly are, and a lot of pharmacies and lawyers don't understand that.

MR. KOZLOWSKI: Right. So Maryland law covers healthcare providers and facilities on original disclosure of information and includes everyone on re-disclosure.

His point importantly is providers holding protected health information need to become familiar with both Maryland state law to determine which legal rule or principle governs at the time you're going to disclose.

Now from a systems standpoint, you know, generic language is there, but there is no shortage of recognition and sensitivity to defining the requirements around access authentication, et cetera. And this has been around a long time and it's being played out at the national level. Its involves the military, as well as civilian interests in trying to come up with something that

is as close to comfortable as possible.

It's ironic that when you sit in these meetings and you talk about access to health information, and if I can, people sit around the water fountain and they talk to people about their medical condition and recent surgery and the problems they're having. But they don't sit around talking about their financial information, but most of the population today uses ATM cards that pushes data worldwide, and they don't seem to have any qualms about it. And in that scenario you could be bankrupt overnight.

So I just offer, don't be too overly-jaundiced in coming up with appropriate protections in the context of medical records because we are doing that in significant other ways every second of every day. We're there already.

JUDGE FADER: Well, first of all, we have had a Confidentiality of Medical Records Act and the instances of that being breached or broken are few and far between.

Secondly, every state you talk to has said that you need to make this a felony for unlawful access or unlawful dissemination of information. Does everybody agree with that or does anybody want to say something?

Now, what does that mean for you, Ramsay, that you had some physicians who accessed people's medical records that you disciplined, accessing this information would be a felony. Accessing the information by those physicians was a crime because here it is right here, except as otherwise provided, the healthcare provider or any other person, this is HG 4-309 (d), who knowingly and willfully violates any provision of this subtitle is guilty of a misdemeanor and on conviction is subject to a fine of not exceeding $1,000 for the first offense and not exceeding $5,000 for each subsequent conviction for a violation of this title.

Now practically if LaRai goes down to Pat Jessamy and says, I think we need to prosecute this

physician, Pat's going to look at her and say, are you nuts, don't you think we have enough to do without doing this?

You don't have to comment on that, LaRai, but I think that's what's going to happen.

MS. EVERETT: All right.

JUDGE FADER: All right. So you have civil and criminal penalties here, but it's a misdemeanor for medical records. It seems to me that we may want to feel that it should be a felony as it is all across the country for access to this database.

DR. FARAH: Probably there are levels and it's hard. There is a distinct difference between a felony and a misdemeanor, because at least we would have to make some drastic changes because basically if you are a felon, you lose your license for all practical purposes. And there is a threshold as to when you want to reprimand and do this and do that, and fine and all that stuff, but still allow somebody to practice under certain

circumstances.

JUDGE FADER: I'm just telling you, and you were at those conferences and you know everybody there said the same thing.

DR. FARAH: Yeah, I know.

JUDGE FADER: An essential part of this is to make it felony. So we're going to have to talk about that and what do we want to do about that?

DR. LYLES: I think a felony to a physician is very burdensome.

DR. FARAH: From a physician standpoint, it is. From a physician's standpoint it has a different situation, but I can see how you've got to have a huge club how people want to try to get through the system. And I have a lot of problem with people accessing stuff they have no business accessing.

DR. LYLES: But a $5,000 fine is a pretty substantial club.

JUDGE FADER: The civil penalties are probably going to be more productive because my

experience with Scott Shellenberger and Sandy O'Connor is they're going to say, are you kidding me, we have so much to do with drug people running around, murderers and things like that, we're going to prosecute this? I don't think it's going to happen.

Any other discussion? All in favor of saying recommending to the legislature that they put in the statute that it should be a felony, raise your hands.

All that say that it should be a misdemeanor?

DR. FARAH: I think it should be according to the egregiousness of the situation.

JUDGE FADER: I don't know what the egregiousness of the situation is, and then you have a problem prosecuting people as to how egregious the situation is going to be. Right, LaRai?

MS. EVERETT: Correct.

DR. LYLES: I can see in a hospital where

this, you know, you access a record and someone complains and all of the sudden this becomes a felony, and what you've lost in the community is something that costs a half a million to train, and you no longer have a provider. And that's what you, we don't want to err toward injury. We don't want the patient injured and we don't want the physician injured.

I think we need to reach some accord where you respect medical records and this is not pursued and breached, but at the same time I have a great deal of difficulty with the felony position on it.

DR. COHEN: Question, if someone could explain why we would want to go beyond the HG 4-309 if that's already in place.

JUDGE FADER: Well, 4-309 that I'm looking at right now talks about crimes involving moral turpitude. From the filing of docket entries with the board and the office of the Attorney General, the board shall order the suspension if the licensee is convicted of or pleads guilty or nolo

to a crime involving moral turpitude. Not all felonies involve moral turpitude.

DR. FARAH: No, exactly. Exactly. Moral turpitude mandates automatic revocation.

JUDGE FADER: I mean I can tell you that running a cocaine den or child pornography out of your garage is a violation of moral turpitude. LaRai, what else could it be? I guess murder is moral turpitude.

DR. FARAH: I have news for you, the board has interpreted moral turpitude for things that conventionally may not have been because we put the bar that we expect a physician above a certain level, but if it was not a physician the comment would apply.

JUDGE FADER: None of which has been appealed to the court.

DR. COHEN: Then we have fraudulently obtaining a record and that's my question is why, if we already have something in place?

JUDGE FADER: Okay, but you have this, but

you're talking about everyone there at that conference saying, and there I'd be interested in what you think about this, that their states have gone because of the confidentiality of medical records, every one of those states has gone, recently enacted a provision of saying that unauthorized and knowing or willful access to these records is a felony.

DR. FARAH: We never asked them how they handle an error. If you have two John Smiths and you go --

JUDGE FADER: It's not willful or intentional.

DR. FARAH: Willful, okay, so there is a way around this kind of thing.

JUDGE FADER: But if Lyles goes back to his office and says Fader was more particularly irritating today than he was in the past and I want to look up his medical record and see what he's on, okay.

DR. COHEN: My reasoning is, is that if

we're considering these to be the equal of medical records and they already have something in law, you would want to change the law then, which is not what our mandate here is. It's change the law for all medical records.

JUDGE FADER: The law now says it's a misdemeanor.

DR. COHEN: Right, but that's a whole other question about do we want to shift all medical records to that or do we just want to say that this is subsumed under that law?

DR. FARAH: Okay. Let's look over the medical piece. What happens if somebody else hacks into the system that's nonmedical?

JUDGE FADER: This is the whole thing.

DR. LYLES: That's more serious.

MS. EVERETT: What if you just do the first one is a misdemeanor, the second subsequent offense upgrades it to a felony.

JUDGE FADER: This says a healthcare provider or any other person.

DR. FARAH: Any other person.

JUDGE FADER: I thought you'd want to take a look at that today.

DR. LYLES: See, I have like two John Faders, and I've got multiple situations in the practice with that.

JUDGE FADER: Then you've got problems.

DR. LYLES: Well, the same names. And in one case I've got the same name and the same birth date but a different year.

JUDGE FADER: Believe me, when we subpoena prisoners, they've brought the father up instead of the son. That can happen.

DR. LYLES: And I have pulled up the wrong record.

JUDGE FADER: That's not willful. Now of course you are also in a situation is that particular point, the bad thing is you may be $20,000 for attorney's fees to prove that. But at the same time, you also have LaRai that's going to tell the detectives, the chances of me getting a

conviction on this are not great. Lyles has an impeccable reputation, this is the first time this has ever happened. This is something that can help, and she's not going to prosecute something like that.

MS. EVERETT: And probably you need more than one instance, too. I think if something like that would come to us, we'd be more like, look, at my investigators, come to me with not only this person, but this person and this person, you know, I think that would be more than just one person.

JUDGE FADER: Mary, what do you think about all this?

MS. ROCHEE: I would say that if it's on that level, we have to go to prosecute a drug case, prosecuting this type of offense as a felony is a no go. I just don't see it happening.

And we have people who are not professionals who perpetrate criminal offenses, and the evidence we're required to come up with, I just don't see us moving forward on something like this.

JUDGE FADER: Well, that's why the civil damages are so important because you can get a lawyer to come in there, you can get attorney's fees, treble damages and things like that and make it worth his while.

DR. FARAH: So misdemeanor with fine up to $100,000.

MR. TAYLOR: Well, here it's fraudulently obtaining records and wrongful disclosure of records, because I think that's the crux of what we are talking about here. And I mean the fines here, 50,000, 100,000, a year in jail, five years in jail, it's pretty substantial, pretty substantial.

DR. FARAH: So you can keep it as a misdemeanor, but besides we need to fund this program at some point in time.

JUDGE FADER: All right. Now let's go over on A, and we're talking about the wiretap law. You know, you're also talking about the fourth estate getting hold of records too because Lyles says, I got this on Fader, I'm going to

deliver it in a brown envelope to a reporter at the socialist Sun, okay. And he's going to send it down there.

Well, here the situation is that what's going to happen as far as those people are concerned and here is your violation of this subtitle in the wiretap law. The state can come in and get an injunction, which is part of the wiretap law. Where's the penalty here? Up above, civil liability, any person whose wire, oral or electronic communication is intercepted or disclosed.

That means the Sun Paper, when they have that in front of them, Don, has to realize where in the hell did this come from, and if they disclose it, okay, they'll also be subject to a fine. Disclosed or used in violation, actual damages but not less than liquidated $100 a day for each or $1,000, and punitive damages, and here is the kicker, a reasonable attorney's fee and other litigation costs.

So the civil penalties are in all those states that say felony, they all have the civil fine and the ability to come in and get attorney's fees, so you'd have to take it on contingency or something.

Now, one of the things we have now in our courts, the federal government a couple years ago and the state government passed laws about all these faxes that people were getting. Everybody was faxing things to people and it was a burden. Well, that's all illegal now and it has attorney's fees with it. And some people are still advertising by fax and the attorneys are coming in on that to get damages and attorney's fees and that has a great prophylactic effect.

So where are we?

DR. FARAH: We're still on the same issue of whether it's a misdemeanor or felony.

JUDGE FADER: We're going to have to address that and we're going to have to say in the report what other states have done, but we also

need to say what we feel this should be.

DR. FARAH: Well, I feel that it probably should be a misdemeanor with a very heavy civil penalty and that the money will be restricted into go back into feeding the program.

JUDGE FADER: Well, we would have a tough time paying this wrongful disclosure and records that are in the present act, we would have a tough time, you know, with all that sort of stuff.

MR. TAYLOR: And I believe, correct me if I'm wrong, but this is each medical record, so that if you look up two different people are you looking at a possible fine of $100,000? So it's per record so it's not just because you went in there and did something illegal. It's per record, so it's a substantial penalty.

JUDGE FADER: All right, LaRai, what do you think about all this? You're not too busy down in that office to handle a few of these a month, are you?

MS. EVERETT: No, I'm not busy at all. In

Baltimore City drug problems are a problem. I kind of like what Bruce was saying, and I think a misdemeanor is more like Mary was saying, it's probably sufficient. I mean a felony I think maybe making it if you have a subsequent offender, like I was suggesting earlier, then it becomes a felony. If you keep doing it and you've been slapped on the hand once, paid a fine and now you're doing it again, but other than that, I think E sounds, I think E. I vote for E. But I think a misdemeanor would probably be more than sufficient with fines attached to it.

JUDGE FADER: All right, everybody finished discussing this one particular point as to whether it should be number one, a felony, or number two, it should be the same penalty provided in HG 4-309 (e), can we put that up?

Okay, number one, how many people feel it should be a felony?

How many people feel that the fraudulent obtaining on HG 4-309 (e) is what should be

incorporated into the law?

Civil penalties, what do you think? Attorney's fees are a must, I respectfully submit. Well, look, I mean I get paid a pension from the state, I'm not doing it anymore. But there's just no way an attorney is going to take this on a contingent basis with having to show damage. So I do not want to go back to practicing law anymore. I don't want to go back to work.

MR. KOZLOWSKI: Does the state put any limits in on attorney's fees?

JUDGE FADER: The state has 147 agents throughout the state that the attorney's fees are all regulated by the judicial branch.

MR. KOZLOWSKI: Okay.

JUDGE FADER: And the state has 147 agents throughout the state who take care of that. They are called circuit court judges, all right. They are the ones who have authority to determine what is reasonable.

You have case decisions to talk about the

lodestar effect. You know, we are really on board in the last couple of years with all that sort of stuff.

DR. LYLES: Not quite as regulated as physicians, but.

JUDGE FADER: No, but I mean a lot of people will come in, they'll take 20 depositions or things like that, and they'll come to me and they'll say, I want reimbursement for this and for that, and I'll say why in the devil did you take 20 depositions? Most of the time you can take two, you know.

DR. COHEN: Say you have a case where you have someone who's been wrongfully hurt, has had information about them obtained and you've got the proof that it was done, it's really a question of whether --

JUDGE FADER: Well, that's compensatory damages. So you can get compensatory damages, punitive damages and then the attorney's fees.

DR. COHEN: But in terms of a legal fee,

what you have is obviously a no-brainer except that you've got to be able to prove that it was that particular person that took the information.

JUDGE FADER: That's correct.

DR. COHEN: But here you can't put the person who is probably wronged at risk and is more likely in probability going to win.

JUDGE FADER: They're going to win, and even if the person proves that the statute was violated by the defendant, they're still by case law entitled to one dollar in damages, which mean that they can get punitive damages and attorney's fees.

DR. COHEN: Okay. So this is really a matter of protecting a person that's wronged in a case where violation of privacy has happened.

JUDGE FADER: That's the situation here.

DR. COHEN: And you don't want to have something in front of them that they can't afford.

JUDGE FADER: No. And I suggest to you that the civil penalty is going to be much more

feared by physicians, and pharmacists and law enforcement people than the criminal penalty.

So what is your pleasure? I suggest that it be compensatory, punitive damages and attorney's fees. Do you want to put a minimum of a $1,000 or anything in there? You know, what do you want to do? Everybody except the Attorney General's office can vote on this because they're salary, they're not on any basis, so we're not going to let you vote to deprive the attorneys of their fees.

All right, what's your pleasure?

DR. FARAH: Well, can't you just include it? Do you think we need to put a minimum?

JUDGE FADER: I don't think we do, but a lot of states do. To me, this is my opinion is compensatory, punitive damages and attorney's fees.

DR. FARAH: Yeah, I would put all of these down because I don't think they're explicit. Especially the legal fees, I think it's important to put that down because sometimes that's missed.

JUDGE FADER: It always says reasonable

attorney's fees.

DR. FARAH: Reasonable attorney's fees. But I am concerned about putting a minimum because it sort of like sets a tempo and I don't particularly care to think it's going to be as cheap as a thousand bucks and I don't think a minimum serves a purpose. I don't think a maximum. I think, as you said, to keep it open and I would put it in bold so that people realize. Because not only the physician, you have so many precedents in our board. I'm worried about the non-physicians using this stuff.

JUDGE FADER: Again, punitive damages are controlled by a case called Campbell, the Supreme Court case which says specifically you cannot use that to bankrupt someone. It must be reflective of what their financial condition is. Now the people in Mississippi have not yet found out what that means, and they've been reversed on it.

All right, does everyone agree that it should be compensatory damages without a specific

money amount? How many feel it should be that?

DR. LYLES: And that's consistent with civil penalties or, you know, actual damages and things like this?

DR. FARAH: Right.

JUDGE FADER: How many feel that you should put punitive damages in there, yes or no? How many say yes? How many say no? Okay. How many you should put attorney's fees in there? Okay, so it's compensatory and attorney's fees.

DR. LYLES: Reasonable.

JUDGE FADER: Reasonable.

MS. EVERETT: And this top thing it says attorney, reasonable attorney's fees and other litigation costs that reasonably incurred.

JUDGE FADER: Other litigation costs, you're right because that includes depositions and so on.

MS. EVERETT: And of course reasonable can be attached to that as well.

JUDGE FADER: Okay. So what are we going

to do about the confidentiality and things of that sort? And this is probably the last thing that we're going to be able to do today. I think we've done well today.

DR. FARAH: What do we need on the confidentiality?

JUDGE FADER: Well, the situation is that we have his statement here, the board policy will establish access levels in a manner to achieve a balance between complexity and stability and administrative overhead.

To me, the legislature is going to want something a hell of a lot stronger than that. Security.

DR. FARAH: I mean you've got to be credentialed in some capacity, all accessees to the system. You've got to have any information that's sent back and forth encrypted. Is that what we're talking about?

JUDGE FADER: Yes, all people must be credentialed for access to the system.

DR. FARAH: Correct. And all data should be encrypted. Because you can't send in a regular email personal health information, and if it's not encrypted, anybody is going to be able to look at it and there's a big strong opportunity for a violation.

DR. LYLES: I'd have to look at the technology.

DR. FARAH: That's how you're going to be sending your emails.

JUDGE FADER: I don't know about the thing for encryption and things like that. I mean I don't know how it's all done. Does anyone else know?

DR. FARAH: Well, I know at United all information that is sent back and forth is encrypted, and any patient information. I'm sure you do, too. That's what I'm saying, how can information, I mean Kaiser would be bankrupt if any information is going to be lost through that.

DR. LYLES: This is not going to be

transmitted over an email server. This is an entirely different type of system.

DR. FARAH: You want to make sure you don't have any hackers having access to this.

DR. LYLES: If you've got a hybrid integrated system like you're talking about, it's difficult, extremely difficult to hack into it.

DR. FARAH: Okay.

DR. LYLES: Because you only get a portion of the data.

DR. FARAH: It's not like in Virginia, correct?

DR. LYLES: No, no, Virginia's got an antiquated system. It's like a hundred years behind. You know, my kid in grade school could write that now.

MR. FRIEDMAN: Well, they are the colonial state.

DR. LYLES: I grew up there.

MR. KOZLOWSKI: One thing I just thought is you don't know what the end product's going to

look like and so the end product is going to determine to some extent how you approach the issues of security and privacy. And so, you know, that's part of the equation. And back when all this was done, there wasn't the impetus and the technology that there is today, so the reality is that you need more definitive point and then come back and say, okay, if this is the way we're going to do it, then based on that, this is how we'll address these issues.

JUDGE FADER: Isn't this one of the main reasons that nothing can be built into the legislation other than general terms here is because constantly technology is being updated and that the multidisciplinary board should have the right to update all of this?

DR. FARAH: Absolutely. And like the state-of-the-art because that's what happened with ASAP.

JUDGE FADER: And how about me extracting from this report on pages 8, 9 and 10 some

buzzwords?

MR. KOZLOWSKI: Would you like, you know, this is a draft which was to writing federal grants for big money, if we just cleaned up 8, 9 and sent it to you with suggestions?

JUDGE FADER: Yes, I'd much rather you put the language in there than me.

DR. LYLES: In the database subcommittee per se, I mean we're looking at things like the elements and organization of the content, database access, permission, every key stroke is audited, all of this will be built into the privacy.

JUDGE FADER: Okay, well if you can do that and put the magic words in and you can put some language in there to the effect that because of changing technology and experience with possible breaches in the past, all that sort of stuff.

MR. KOZLOWSKI: Can I just ask if you all take the time to read this before we get back together, I think it'll make subsequent discussions a lot easier.

JUDGE FADER: All right. Here's where my memos left off, question one is what drugs are included. Question two is do we do this through regulations or through the secretary. Question three is who the dispensers shall be. Question four, the data that shall be submitted. Question five is the legislative statement to the effect that things should be electronically submitted but exemptions will be given. Question six is what the magic word shall be for an event where law enforcement and disciplinary people may have access to the information for practitioners, its medical need.

Question seven is patient access. That would come through the regulations, provisions that would be enacted and applications there and the patient would not be able to change the record.

Question eight, determine how to ensure the material is kept confidential. We have the Bruce language and Sharp language. Penalty's not to be a felony but to be a misdemeanor, and we'll

track the language in the access to documents. And then civil penalties, we'll track the language there. We will not include punitive damages, okay. But all of these things are there and when we vote on them, you know, one of the things I think I'm going to say is that I think punitive damages should be in there so I will say that I'm entitled to a footnote, okay, and other people that don't agree with all of these things will be entitled to their footnotes. We'll tell them how many people voted this way and how many people voted that way. And that to me, is a good day's work.

DR. LYLES: Before you guys leave, this is a copy of some generic considerations for databases. Taking a look at that.

JUDGE FADER: We have to get it into the committee reports from the last time, too.

DR. LYLES: We can do that next time.

JUDGE FADER: Georgette and I will work on that this week and see what we can do to add you

all.

All right, anybody else have anything you want to say? The next meeting is November 6th.

MR. FRIEDMAN: And then the meeting after that is December 4th.

JUDGE FADER: Okay, she wants me again to say anybody that would like to go to San Diego.

MS. ZOLTANI: Please let me know because your whole trip will be covered.

DR. LYLES: First class?

JUDGE FADER: Thank you all very much.

(The meeting was adjourned at 12:20 p.m.)